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Statement of
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Pearson-Health Claims

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The Question posed:

Should health claims go beyond claims about reducing the risk of a disease to include claims about mitigation or treatment of an existing disease, or are such claims drug claims? Where is the boundary, if any, between these claims?

Good afternoon. I am Regina Hildwine, Senior Director of Food Labeling and Standards with the National Food Processors Association.

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruits and vegetables, meat and poultry, seafoods, drinks, and juices or provide supplies and services to food manufacturers.

One does not have to stray far from the text of the Federal Food, Drug, and Cosmetic Act to find the correct answer to the first question asked of this panel. The statute authorizes substantiated food claims that "characterize[ ] the relationship of any nutrient . . . to a disease or health-related condition . . .." [21 U.S.C. 343(r)(1)(B)]. We have come to call this category of food claims "health claims," but the authorizing provisions in the Act, which were adopted through the 1990 Nutrition Labeling and Education Act, were put forward in an

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effort to counteract FDA's preexisting categorical ban of all disease claims for foods under the drug definition, section 201(g)(1)(B) of the Act. That definition notes that a drug is an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . .."

Notably, in elaborating the NLEA provisions, Congress made no effort to limit the nature of disease claims that were approvable as "health claims" to claims about prevention or risk reduction. To the contrary, the Congress deliberately adopted broad language which embraces the full spectrum of potential relationships between nutrients and disease, including all those relationships that are named in the drug definition, at section 201(g)(1)(B). Claims "characterizing" the "relationship" between nutrients and disease plainly could include not only preventive relationships, but mitigation, treatment, cure, and perhaps even diagnosis. The only question that is relevant is whether the relationship that is claimed is properly substantiated. And if it is, the statute says FDA "shall" authorize the claim [21 U.S.C. 343(r)(3)(B)]. The health claim provisions go on to include conforming amendments to ensure that foods bearing authorized health claims cannot be regulated as "drugs" under section 201(g)(1)(B).

So the bottom line is that FDA lacks any authority to confine health claims to those expressing a specific type of diet-disease relationship. FDA's authority must be directed toward ensuring that claims are properly substantiated and are stated in a truthful and nonmisleading manner in view of the nature of all available substantiating evidence.

FDA, in asking these questions today, appears to signal that it believes that certain types of claims are appropriate for foods. This thinking reflects an arbitrary value judgment – and appears to be the kind of paternalism that the court in *Pearson v. Shalala* so soundly rejected. The *Pearson* court made it clear that the government – specifically FDA – must not stand as a gatekeeper restricting the flow of truthful, nonmisleading information. To justify restrictions on label information , the restrictions must relate directly to alleviating real harms that the information itself otherwise would inflict.

Advancing science has shown that many "lines" that might be drawn between "prevention," "treatment," and "mitigation" are at best fluid - if they exist at all. FDA's own regulations for foods for special dietary use make the point. Those regulations recognize that foods can be an important part of managing disease by addressing particular physiological needs that exist "by reason of physical, physiological, pathological, or other condition(s)" (21 C.F.R. 105.3). Foods and nutrients that help prevent disease frequently also mitigate and even treat disease. If consuming a food as a food is potentially helpful in relationship to disease, that information can be communicated lawfully to consumers through food labeling. We must get away from arbitrary line drawing exercises that have no scientific or legal basis, and are destined to failure in the end.

So, the short answer to the question, "should health claims go beyond claims about reducing the risk of a disease to include claims about mitigation or treatment," is **YES**. There is no basis for doing otherwise.

The question certainly provokes a great deal of thinking about the role of foods and nutrients in foods in preventing and treating diseases and mitigating symptoms. For example: Can a high fiber cereal be included as part of a treatment plan for certain digestive disease, like diverticular disease? Is it true that a diet with controlled levels of calories, carbohydrates, and other nutrients is useful in managing non-insulin dependent diabetes mellitus? Can some patients manage their type 2 diabetes through diet alone? Could eating chicken soup be effective in providing temporary relief from the symptoms of the common cold? Can dietary calcium do more than merely reduce the risk of osteoporosis? I'm sure many of you know what the recent NIH consensus conference had to say on that point. Can dietary calcium be used to treat orthopedic conditions other than reducing risk of osteoporosis?

For the last of these questions I am going to tell you a personal anecdote. A few months ago, I fractured two bones in my arm, the result of a clumsy fall – simple, non-displaced fracture, but two broken bones nonetheless. The standard, and even time-honored, treatment for simple fractures is reduction, immobilization, pain alleviation, and time. But at my first consultation with my orthopedist, he asked me if I was a milk drinker, and was pleased when I said yes. He told me to be sure to keep my calcium up, get 100% of the RDA [he used the old terminology], take a calcium supplement if I have to. From that moment, I considered dietary calcium to be part of the treatment of my fracture. I did not need to see reams of scientific studies to persuade me to follow a course that, to me, made perfect sense. After all, if it is well accepted that calcium helps build strong bones – the quintessential structure-function claim for foods – it was logical to me that calcium might provide some beneficial effect to help rebuild bone injured through fracture. If such a claim could be hypothesized for foods, even in concept, it could create an opportunity for some serious scientific research – and soon we could even see milk bars on the ski slopes!

Are all orthopedists as aware of dietary factors as the one that first treated me – even about a substances as elemental to the profession as calcium? I doubt it. The challenge then becomes how to make physicians as aware of the usefulness of dietary factors for treatment as they are about drugs – so they can advise their patients on the potential health benefits of foods in the treatment of their conditions. Fortunately, the First Amendment environment is now more amenable to meeting this challenge.

From fiber to chicken soup to dietary calcium, people have been using foods to help treat or mitigate the symptoms of diseases from the beginning of time. Everyone has to eat, so why not eat something that may help with your particular

condition? This is an area of vigorous scientific research, and the body of evidence is growing that could be used to substantiate such beneficial claims.

It is another matter entirely for FDA to authorize a health claim for food labeling along these lines, since the agency has typically interpreted the health claims provisions to be limited to risk reduction. Through this approach, FDA has adopted an overly broad interpretation that places undue impediments before structure-function claims for conventional foods that should require no FDA pre-approval. The history behind the dental caries/sugar alcohol health claim – which appears at its foundation actually to be a nutrient avoidance claim coupled with a structure-function claim – raises many questions. In FDA's recent rulemaking on structure-function claims for dietary supplements, the tension between FDA's policy on implied health claims and structure-function claims has grown increasingly obvious. Heart symbols on food labels have been regulated as health claims in need of the safeharbor of prior approval, while FDA says that "CardioHealth" is a structure-function claim.

This internal inconsistency and arbitrary line drawing by FDA illustrates the need for a new way of thinking – a paradigm shift. And FDA is under the *Pearson* court's order to create that shift by making room for the free flow of truthful nonmisleading claims, and confining restrictions to those needed to remedy the concrete harms presented by fraudulent and deceptive claims.

The time has come for FDA to embrace the First Amendment.

The statutory language on health claims defines the scope of the vessel – say, a glass. FDA in its implementing policies and regulations has filled the glass only about one quarter full. There is much more room in the glass than FDA has been prepared to fill. The *Pearson* court tells us that the government must not be so restrictive when people thirst for truth. We urge FDA to open up the flood gates and let truthful, non-misleading information flow.

Thank you.